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**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



REC'D 23 MAY 2006

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Applicant's or agent's file reference <b>PCTA9411-6</b>	<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416
International application No. <b>PCT/KR2004/003517</b>	International filing date(day/month/year) <b>30 DECEMBER 2004 (30.12.2004)</b>	Priority date (day/month/year) 17 JANUARY 2004 (17.01.2004)
International Patent Classification (IPC) or national classification and IPC  <b>C12Q 1/68(2006.01)i</b>		
Applicant  <b>Korea Research Institute of Bioscience and Biotechnology et al</b>		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.
3.	<p>This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p style="margin-left: 20px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 20px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>
4.	<p>This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>

Date of submission of the demand  <b>18 OCTOBER 2005 (18.10.2005)</b>	Date of completion of this report  02 MAY 2006 (02.05.2006)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer  SHIN, Kyeong A  Telephone No. 82-42-481-5589 

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/003517

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☒ This report is based on translations from the original language into the following language English which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☒ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☐ the description:  
 pages \_\_\_\_\_ as originally filed/furnished  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_ as originally filed/furnished  
 pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_ as originally filed/furnished  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/003517

## Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1 - 17	YES
	Claims	None	NO
Inventive step (IS)	Claims	1 - 17	YES
	Claims	None	NO
Industrial applicability (IA)	Claims	1 - 17	YES
	Claims	None	NO

### 2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

- D1: WO 2002/072821 A (INCYTE GENOMICS, INC.) 19 Sep. 2002
- D2: WO 1999/49028 A (GENENTECH, INC.) 30 Sep. 1999
- D3: KLEIN, R. D. ET AL. "Selection for genes encoding secreted proteins and receptors." Proc. Natl. Acad. Sci., Jul. 1996, Vol.93, pp. 7108-7113.
- D4: DOWNING, K. J. ET AL. "Staphylococcus aureus nuclease is a useful secretion reporter for mycobacteria," Gene, 1999, Vol.239, pp. 293-299.
- D5: LIM, E. M. ET AL. "Identification of Mycobacterium tuberculosis DNA sequences encoding exported proteins by using phoA gene fusions." J. Bacteriol., Jan. 1995, Vol. 177(1), pp. 59-65.
- D6: MACCONAILL, L. E. ET AL. "Investigation of protein export in Bifidobacterium breve UCC2003." Appl. Environ. Microbiol., Dec. 2003, Vol.69(12), pp. 6994-7001.
- D7: WO 2001/00806 A (GENSET) 04 Jan. 2001
- D8: TAN, N. S. ET AL. "Engineering a novel secretion signal for cross-host recombinant protein expression." Protein Eng., 2002, Vol.15(4), pp. 337-345.

### I. Novelty & Inventive Step

The subject matter of claims 1 and 8 relates to a method for screening a translational fusion partner (TFP) for producing a non-producible protein comprising: (a) preparing an automatic screening vector including a report gene linked with a gene encoding a non-producible target protein; (b) linking a gene library including a TFP to the automatic screening vector to create a TFP library; (c) transforming cells having no activity of the reporter gene with TFP library; and (d) isolating a gene from transformed cells exerting the activity of the reporter protein.

(Continued to Supplemental Sheet.)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
- a. type of material
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☒ on paper
    - ☒ in electronic form
  - c. time of filing/furnishing
    - ☒ contained in the international application as filed
    - ☒ filed together with the international application in electronic form
    - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
    - ☐ received by this Authority as an amendment\* on \_\_\_\_\_
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed of furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

**Supplemental Box**

In case the space in any of the preceding boxes is not sufficient.  
Continuation of:

Box. No. V

D1 to D6 disclose a method for screening signal (secretion) peptide. D1 to D6 use a gene encoding signal peptide linked to a reporter gene and fail to disclose or suggest additional linking of non-producible protein to a reporter gene fused to signal peptide.

As described in the present invention, additional linking of a gene encoding non-producible protein remarkably reduces the number of transformants expressing a reporter gene, thereby gives better specificity and sensitivity.

Therefore, the subject matter of claims 1 and 8 is novel and involves an inventive step (PCT Article 33(2) and 33(3)). Claims 2 to 7 and 14 are dependent claims of claim 1, so they are also novel and involve an inventive step (PCT Article 33(2) and 33(3)).

The subject matter of claims 9 and 10 relates to TFP proteins and genes encoding them. D7 and D8 disclose some signal peptide. However, D7 or D8 fails to disclose a specific DNA or amino acid sequence with significant sequence homology with the one provided from the present invention. Therefore, the subject matter of claims 9 and 10 is novel and involves an inventive step (PCT Article 33(2) and 33(3)). Claims 11 to 13 and 15 to 17 are dependent claims of claim 9 or claim 10, so they are also novel and involve an inventive step (PCT Article 33(2) and 33(3)).

Accordingly, claims 1-17 of the present invention are novel and involve an inventive step (PCT Article 33(2) and 33(3)).

## II. Industrial Applicability

Claims 1-17 of the present invention are industrially applicable (PCT Article 33(4)).